JUL 9 2002

SECTION 14
510(K) SUMMARY

FOI RELEASABLE

Pursuant to §513(I)(3)(A) of the Food, Drug, and Cosmetic Act, Boston Scientific Corporation is required to submit with this Premarket Notification "...adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Boston Scientific Corporation chooses to submit a summary of information respecting safety and effectiveness.

Date:	December 28, 2001
Common/Usual Names:	Tube, Gastrointestinal Tube, Gastro-Enterostomy
Trade/Proprietary Names:	- Endovive™ Initial Placement Gastrostomy Kit - Securi-T Initial Placement Gastrostomy Kit - Endovive™ Low Profile Button Replacement Gastrostomy Tube
Classification Name & Device Classification:	Class II

Name	Number	21CFR Ref.
Tubes, Gastroint. & Acc.	78 KNT	876.5980
Tube, Gastro-Enterostomy	78 KGC	876.5980

Device Panel/Branch:	Gastroenterology-Urology (GU) Gastro-Renal (GRDB)
Owner/Operator:	Boston Scientific Corporation One Boston Scientific Place Natick, MA 01760
Contact Person:	Paige Sweeney Regulatory Affairs Specialist

Description of Devices

The Endovive™ Initial Placement Gastrostomy Kit and the Securi-T™ Initial Placement Gastrostomy Kits are used during initial placement for direct feeding, and the Endovive™ Low Profile Button Replacement Gastrostomy Tube is used for the replacement of direct feeding tubes used for direct feeding.

Indications for Use

The Endovive™ Initial Placement Gastrostomy Kits (Guidewire & Pull) and the **Securi-T™ Initial Placement Gastrostomy (Guidewire & Pull)** are indicated to provide nutrition directly into the stomach in adult and pediatric patients who are unable to consume nutrition by conventional means.

The Endovive™ Low Profile Button Replacement Gastrostomy Device is indicated to provide nutrition directly into the stomach through the stoma. It is indicated for use in adult and pediatric patients who are unable to consume nutrition by conventional means.

Descriptive and Technological Characteristics of Proposed and Predicate Devices

Boston Scientific Corporation believes that the Endovive™ Initial Placement Gastrostomy Kit, the Securi-T™ Initial Placement Gastrostomy Kit, and the Endovive™ Low Profile Button Replacement Gastrostomy Device, are substantially equivalent to the currently marketed Endovive™ Initial Placement Gastrostomy Kit, the Securi-T™ Initial Placement Gastrostomy Kit , and the Endovive™ Low Profile Button Replacement Gastrostomy Device, and the Endovive™ Low Profile Initial Placement Gastrostomy Kit. The major components of these devices are the internal bolster and the gastrostomy tube. A thorough comparison of the descriptive characteristics between the proposed gastrostomy devices and the predicate devices show equivalence.

Performance Characteristics

The proposed devices are identical to the predicate devices and therefore, no additional performance testing was performed.

Conclusion

Boston Scientific Corporation has demonstrated that the Endovive™ Initial Placement Gastrostomy Kit, the Securi-T™ Initial Placement Gastrostomy Kit, and the Endovive™ Low Profile Button Replacement Gastrostomy Tube are substantially equivalent to the currently marketed Endovive™ Initial Placement Gastrostomy Kit, the Securi-T™ Initial Placement Gastrostomy Kit, the Endovive™ Low Profile Button Replacement Gastrostomy Tube, and the Endovive™ Low Profile Initial Placement Gastrostomy Kit.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 9 2002

Ms. Paige Sweeney
Regulatory Affairs Specialist
Microvasive Endoscopy
Boston Scientific Corporation
One Boston Scientific Place
NATICK MA 01760-1537

Re: K014297
Trade/Device Name: Endovive™ Initial Placement Gastrostomy Kit
Endovive™ Low Profile Button Replacement Gastrostomy Tube (Button™)
Securi-T™ Initial Placement Gastrostomy Kit
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: 78 KNT
Dated: April 9, 2002
Received: April 10, 2002

Dear Ms. Sweeney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note*: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all

the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

In addition, we have determined that your device kit contains iodine swabs, lubricating jelly, antibiotic ointment, and 1% Xylocaine, which are subject to regulation as drugs.

Our substantially equivalent determination does not apply to the drug components of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug components. For information on applicable Agency requirements for marketing these drugs, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/dsma/dsmamain.html

Sincerely yours,

for Nancy C. Brogdon
Director Division of Reproductive, Abdominal,
and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K014297

SECTION 3
INDICATIONS FOR USE

510(k) Number: To Be Determined

Device Names:
- Endovive™ Initial Placement Gastrostomy Kit
- Endovive™ Low Profile Replacement Gastrostomy Tube
- Securi-T™ Initial Placement Gastrostomy Kit

Indications for Use: **The Endovive™ Initial Placement Gastrostomy Kits (Guidewire & Pull)** and the **Securi-T™ Initial Placement Gastrostomy Kits (Guidewire & Pull)** are indicated for adult and pediatric populations to provide nutrition directly into the stomach in patients who are unable to consume nutrition by conventional means.

The Endovive™ Low Profile Button Replacement Gastrostomy Tube is indicated in adult and pediatric populations to provide nutrition directly into the stomach through an existing stoma. They are indicated for use on patients who are unable to consume nutrition by conventional means.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use** ____
(Per 21CFR 801.1091) **(Optional Format 1-2-96)**

David G. Segura

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K014297